The Voice of Natural Health Consumers
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November 22, 1999

Jane Henney, MD
Commissioner
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm. 1061
Rockvillc MD 20852

Docket Nos. 91N-0101, 91N-0098, 91N-0103, and 91N-100H

Dear Commissioner Henney:

Citizens For *Health* is submitting comments in response to the Food and Drug Administration's (FDA) request for information for evaluating the scientific evidence related to the following four health claims: 1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer," 2) "Consumption of fiber may I-educe the risk of colorectal cancer," 3) "Consumption of omega-3 fatty acids may reduce thc risk of coronary heart disease," and 4) "0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

These four health claims were the subject of the lawsuit Pearson, et. al. v. Shalala in which *Citizens* was a co-plaintiff. The United States Court of Appeals rendered a decision in the case requiring FDA to define the term "significant scientific agreement" for health claims on dietary supplement labels and to allow the use of disclaimers in making health claims.

We understand that FDA's September 8, 1999 Notice is a solicitation for more scientific evidence associated with the four health claims. However, *Citizens* is concctned that FDA is not implementing the intent of the Appeals Court's decision. We believe that FDA's priority should be defining "significant scientific agreement" as directed by the Appeals Court and establishing criteria for acceptable disclaimers so that the multitude of scientific evidence already submitted on these four health claims can be organized, evaluated, and disseminated. Until these standards -- standards against which to weigh submitted science -- are in place, WC believe FDA is premature in soliciting information to "reevaluate scientific evidence" for these four claims.

Citizens has provided FDA in hearings this summer and directly to Joe Levitt, director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), our policy paper regarding dietary supplement policy, "An Opportunity to Lead: Overall Strategy for FDA Regulation of Dietary Supplements Through Sound Information Rules." We are including in our submitted comments the part of that document addressing thc "significant scientific agreement" issue.

91N-0098 C120

Significant Scientific Agreement
(from "An Opportunity to Lead: Overall Strategy for FDA Regulation of Dietary Supplements Through Sound Information Rules," pages 5-6)

Citizens *For Health* strongly urges FDA lo oncourage the broadest possible availability of health benefit information on the labels of dietary supplements as thc primary way to ensure that consumers get the widest choice of the safest nutrients availablc in the market.

With interest in dietary supplements crossing age, racial, economic, and educational divisions, consumers are demanding more opportunities to inform themselves about the health benefits of supplements. Expanding the use of health claims is an important aspect in fulfilling thc Congressional and public intent in passage of DSHEA. Consumers want the opportunity to rake control of their own health. The public has shown time again with their dollars and their voices that they want to USC dietary supplements and that they arc willing to tight for thc right t.o make informed health choices.

FDA's continued insistence on banning health claims that are generally accepted by the scientific community until they are conclusively proven to a standard virtually indistinguishable from that required of a new drug has had unacceptable consequences on consumer health. Such action led to the deplorable situation where FDA's failure to approvc widely accepted scientific claims for folic acid's prevention of birth defects may have led to as rnany as 2,500 children suffering damage that could havc been prevented through consumption of folic acid.

The Presidential Commission on Dietary Supplement Labels, mandated by DSHEA, has also challenged thc FDA's narrow interpretation of "significant scientific agreement." The Commission statement included:

- "the standard of scientific agreement should not be so strictly interpreted as to require unanimous or near-unanimous support."

- "FDA should ensure that broad input is obtained to ascertain thc degree of scientific agreement that exists for a particular health claim" and "the USC of appropriule panels of qualified scientists from outside the agency is encouraged"

- "that Consumer understanding of nutritional support and health claims are important aspects of the information that require additional and continued assessment"

The FDA Reform bill passed in November *1997* expanded the assessment of what health claims might be allowed, and allows health claims to be made on dietary supplement labels if a scientific body of the federal government, like NIH or CDC, has published an "authoritative statement" on the nutrient-disease relationship on which the claim is based. However, this provision does not make real advances in allowing health claims, because PDA continues to have the final word on approving the applications for health claims on labels. Additionally, FDA still must define its "significant scientific agreement" standard for the health claim applications that have not been addressed by a "scientific body" of the federal government.

Citizens urges that the agency immediately address the definition of "significant scientific agreement" as ordered by the US Court of Appeals in its ruling in Pearson v. Shalala.

Additionally, *Citizens* believes that the USC of disclaimers, such as those considered by the Appeals Court in the Pearson v. Shalala case, should be considered in determining what requirements should apply to health claims based on "authoritative statements."

Citizens urges the overarching policy that the full, robust flow of information is the best way to create both safety and choice for the consumer. In every instance in which FDA looks at a health statement on a label it should expand the opportunity for information to be made available to the consumer.

FDA should permit on labels statements that arc supported by "significant scientific agreement," including but not limited to "authoritative statements," even if they ate preliminary suggestions about possible health benefits, as long as their nature is indicated.

Citizens believes this policy statement is applicable to FDA's September 8, t 999 *Federal Register* Notice. We hope FDA takes these views into consideration as the agency considers the action steps regarding these four health claims.

Sincerely,

Susan Haeger
President/CEO

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To: FDA Dockets Fax No. 301 827 6870

Company: 91N-0101, 91N-0098, 91N-0103, 91N-100H

From: Shannon Brown

Comments: Food Labeling; Health Claims and Label Statements. Request for Scientific Data and Information

CROSS FILE SHEET

File Number: 91N-100H/C101

See File Number: 91N-0103/C119

91N-0101/C176

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